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16 August 2000

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Commissioner Jane Henney
Food and Drug Administration
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, MD 20852

RE: Docket No. 98P-1194

Dear Commissioner Henney:

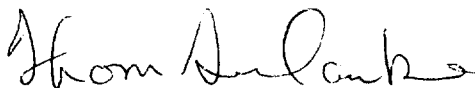
On January 19, 1999, the Center for Food Safety and numerous other organizations and individuals filed a legal petition with the Food and Drug Administration (FDA) asking that the approval of genetically engineered bovine growth hormone (rBGH) (also known as rBST or Posilac) be withdrawn. As a concerned citizen, I am writing to request that you immediately remove rBGH from the market.

In 1999, scientists from Health Canada found that the FDA failed to investigate studies showing that rBGH could lead to potential human health problems. In particular, these pre-approval studies found that the oral feeding of rBGH led to thyroid cysts and prostrate activity in male rats. The study also concluded that significant animal health problems were associated with rBGH use in dairy cows including a 50% risk increase of lameness and a 25% risk increase in mastitis (udder infections). This new analysis has confirmed earlier scientific studies and provided evidence that milk and dairy products derived from rBGH-treated cows pose significant potential human health impacts such as increased cancer risks and the development of antibiotic resistance.

We have a fundamental expectation that the FDA will act to protect the American public by ensuring the safety and quality of our food supply. I find it particularly appalling that the FDA allows rBGH on the market even though Canada and the European Union refuse to approve this dangerous product because of the clear findings of potential risk. It is my understanding that the Food, Drug and Cosmetic Act mandates that evidence of imminent health hazards caused by animal drugs, such as those revealed about rBGH, require the FDA to withdraw such products from the market. I support the Center for Food Safety and other organizations that have filed a legal petition seeking that the FDA fulfill this legal obligation.

I request that you please take immediate action to remove this potentially hazardous product from the market. Thank you.

Sincerely,



Thom Sulanke
98P-1194

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